HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

M4010N

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –3863-0
July 26, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gregory Campbell
Supervisor of Radiology
Women's Health Center
1280 North Court St.
Circleville, OH 43113

Facility I.D.#: 203315

Dear Mr. Campbell:

We are writing to you because on July 6, 2000, your facility was inspected by a representative of the State of Ohio, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

1. Your records revealed that your facility processed mammograms when the processor quality control records for your Kodak M35A processor were missing for seven consecutive days. **21 CFR 900.12(e)(1)(i)-(iii)**

2. Your records showed that your facility processed mammograms when the processor quality control records were missing seven of 21 days or 33% of total days of operation in October 1999. **21 CFR 900.12(e)(1)(i)-(iii)**

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, these conditions represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violations noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violations.

Please include sample records with an explanation that demonstrates proper record keeping procedures that are now being followed. (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Stacey Melick
Ohio Department of Health
Radiologic Technology Section
246 North High St., Fifth Floor
Columbus, OH 43215

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address all other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Carol A. Heppe
Acting District Director
Cincinnati District Office